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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,425	01/26/2001	Xaveer Van Ostade	4644US	8053

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09/29/2003

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,425

Applicant(s)

OSTADE ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-16, 18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-16, 18 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' Amendment

Applicants' amendment in Paper No. 21 filed on July 28, 2003 has been entered in full. Claims 11 and 15 have been amended. Claims 1-11, 14-16, 18, and 21-25 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Under 35 U. S. C. § 112, 2nd paragraph

The rejection of claims 11, 15-18, 24 and 25 under 35 U.S.C. 112, 2nd paragraph set forth in the record (Paper No. 20) remains. The claims are indefinite because the steps recited by the methods do not necessarily achieve the goal set forth in the claim preamble. It is noted that claims 11 and 15 have been amended. However, the amended claims do not overcome the rejection for the reasons set forth in Paper No. 20.

Applicants argue, citing case law, that the method steps of claims 11, 14-18, 24, and 25 do not have to achieve the goal set forth in the preamble, but definiteness requires that the steps of the method are capable of performing the language set forth in the

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preamble. This has been fully considered but is not deemed to be persuasive for the following reasons. First, the case law refers to a device, whereas the instant claims refers to a screening method. Secondly, claim 11 recites a method of screening a compound that inhibits the binding of a ligand; claims 15 and 18 recite a method of screening for ligands of an orphan receptor; whereas claims 24 and 25 recite a method of screening for antagonists inhibiting ligand-receptor binding. However, the method steps never require measuring and/or comparing the binding of a ligand to a chimeric receptor in the presence or absence of a test compound. Thus, the steps of the method are not capable of performing the goal set forth in the preamble, rendering the claims indefinite. It is further noted that claim 11 recites, in part, a method of screening a compound that *inhibits the binding of a ligand with the signaling pathway* of the cytoplasmic part of a chimeric receptor. It is unclear what are the metes and bound of the claim.

Applicants argue that it is well known in the art that screening systems may give false positives or negatives, wherein the screening is confirmed by another test. Applicants further submit that patents claiming yeast two-hybrid screening methods, which may result in false positives, have issued. This has been fully considered but is not deemed to be persuasive because the claimed methods lack steps of measuring and/or comparing the binding of a ligand to a chimeric receptor in the presence or absence of a test compound and thus are not capable of performing the goal set forth in the preamble. Here, it is not an issue of whether a screening method gives false positives or

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negatives; instead, it is an issue about incomplete steps of the claimed method. Thus, the Applicants' argument is irrelevant.

The Examiner notes that it is well settled that the prosecution of one patent application does not affect the prosecution of an unrelated application. In *re Wertheim*, 541 F.2d 257,264,191 USPQ 90, 97 (CCPA 1976) (holding that "[I]t is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others"). Accordingly, Applicants' argument with respect to the other patents issued by PTO is unavailing.

Claim Rejections Under 35 U. S. C. § 103 (a)

(i) The rejection of claims 1-6, 10, 11, 14-16, 18, and 21-25 under 35 U.S.C. 103(a) as being unpatentable over Pestka et al. (WO 98/02558, January 22, 1998) in view of Trueheart et al. (*IDS*, WO 98/13513, April 2, 1998), set forth in Paper No. 20, remains.

At the middle of page 7 of the Applicants' response, Applicants argue that a *prima facie* case of obviousness has not been established with regard to claims 1-6, 10, 11, 14-16, 18, and 21-25 since no suggestion or motivation exists to combine the cited references.

This has been fully considered but is not deemed to be persuasive because the previous Office action (Paper No. 20, June 11, 2003) clearly indicates the motivation of combining the teaching of Pestka et al. with the teaching of Trueheart et al. That is, it

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would have been obvious to one having ordinary skill in the art at the time the invention was made, as a matter of choice, instead of exogenous addition of a test compound to cells, to use a second gene encoding a compound taught by Trueheart et al. so that a compound can be expressed, an autocrine or anti-autocrine loop can be created in cells taught by Pestka et al., and such cells can be used for the screening method taught by Pestka et al. with a reasonable expectation of success. One would have been motivated to do so because endogenous expression of polypeptides in a cDNA library allows rapid screening of large numbers of polypeptides as taught and by Trueheart et al. (see, e.g., page 3, last paragraph). It would have also been obvious to one having ordinary skill in the art at the time the invention was made to apply the screening method taught by Trueheart et al. in identifying a specific ligand, an agonist, or an antagonist for the chimeric receptors taught by to with a reasonable expectation of success. One would have been motivated to do so because the chimeric receptors can be readily expressed in cells and used for screening their ligands, agonists, or antagonists, as demonstrated by Pestka et al.

The Examiner notes that it is the benefit of the methods taught by Pestka et al. and Trueheart that motivates one skilled in the art to combine the teaching of Pestka et al. with the teaching of Trueheart et al. It is unnecessary that the claimed invention be expressly suggested in any one or both references to justify combining their teachings; rather, the test is what the combined teachings of the references would have suggested

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to those of ordinary skill in the art In re Keller, 642 F.2d 413, 288 USPQ 871 9ccpa 1981).

Beginning at the bottom of page 7 of the Applicants' response, Applicants argue that a *prima facie* case of obviousness cannot be established since one of ordinary skill in the art would not have a reasonable expectation of success in combining Pestka et al. with Trueheart et al. Applicants also submit that when considering the claimed invention as a whole, one skilled in the art would not expect the chimeric receptor of Pestka et al. to function in the yeast cells of Trueheart et al. Applicants further submit that one skilled in the art would not expect the autocrine loops including the G-protein coupled receptors of Trueheart to function in the cells of Pestka et al. since the cells of Pestka et al. include several hundreds of GPCRs.

This has been fully considered but is not deemed to be persuasive for the following reasons. Pestka et al. teach numerous chimeric receptors for cellular activation and methods for identifying a specific ligand, an agonist, or an antagonist using routine screening techniques and a highly sensitive assay cell line that express a chimeric receptor, whereas Trueheart et al. teach expression of a large number of polypeptides in a library in a cell to identify those polypeptides that agonize or antagonize receptor bioactivity, creating an autocrine system. Trueheart et al. not only teach activation of the pheromone pathway in yeast by heterologous receptors, but also teach the use of other types of cells (including eukaryotic cells) as host cells and the use of several target

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receptors such as cytokine receptors, receptor tyrosine kinases, and G-protein coupled receptors. With the extensive teachings in the art, including those of Pestka et al. with Trueheart et al., the claimed invention as a whole would have been obvious to an artisan. One skilled in the art would be able to combine the chimeric receptors taught by Pestka et al. with the autocrine loops taught by Trueheart et al. in different ways with a reasonable expectation of success.

At the bottom of page 8, Applicants argue that Trueheart et al. recognize that wild-type gene would frustrate genetic selection because of the background produced by the wild-type gene, and thus teaches away from combining the teachings of Trueheart et al. with Pestka et al. Applicants further argue that the cells of Pestka et al. would be expected to produce a background that may make screening the mammalian cells nearly impossible.

This has been fully considered but is not deemed to be persuasive because an artisan would be able to evaluate the background to determine whether it is appropriate to use a specific phenotype or a mammalian cell for the screening method, with the extensive teachings of Pestka et al. and Trueheart et al. Thus, the recognition of potential background produced by a wild-type gene does not teach away from combining the teachings of Trueheart et al. with Pestka et al.

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(ii) The rejection of claims 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Pestka et al. (WO 98/02558, January 22, 1998) in view of Trueheart et al. (WO 98/13513, April 2, 1998), and further in view of Pellegrini et al. (*Molecular and Cellular Biology* 9:4605-4612, 1989), as set forth in Paper No. 20, remains.

Applicants argue claims 7 and 8 are non-obvious, at the very least, as directly or indirectly depending from non-obvious independent claim 1. This has been fully considered but is not deemed to be persuasive because claim 1 is obvious over the teachings of Pestka et al. and Trueheart et al. for the reasons set forth above and in Paper No. 20.

(iii) The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Pestka et al. (WO 98/02558, January 22, 1998) in view of Trueheart et al. (WO 98/13513, April 2, 1998), and further in view of Mizushima et al. (*Nucleic Acids Research*, 18:5322, 1990), as set forth in Paper No. 20, remains.

Applicants argue claim 9 is non-obvious, at the very least, as indirectly depending from non-obvious independent claim 1. This has been fully considered but is not deemed to be persuasive because claim 1 is obvious over the teachings of Pestka et al. and Trueheart et al. for the reasons set forth above and in Paper No. 20.

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Conclusion

No claims are allowed.

Advisory Information

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
September 24, 2003


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